Emily Brown Rosen
Organic Research Associates
P O Box 5 Titusville, NJ 08560
ebrownrosen@earthlink.net

Eric Sideman
31 Anson Rd. Greene, ME 04236
esideman@mofga.org

Arthur Neal
Director of Program Administration
National Organic Program
USDA-AMS-TMP-NOP
1400 Independence Ave., SW, Room 4008 So.
Ag Stop 0268
Washington, D.C. 20250
Sent Via E-Mail to: National.List@usda.gov

RE: Docket No. TMD-04-01
Comments on Proposed Amendments to the National List
of Allowed and Prohibited Substances, 7 CFR Part 205

November 14, 2005

Dear Arthur Neal:

Thank you for the opportunity to comment on the proposed amendments to the USDA National List of Allowed and Prohibited Substances (National List), Docket Number TMD-04-01. We write as a consultant who works in organic certification regarding products and materials for use in organic production, and as a former NOSB member who provides technical advice to organic farmers. We are pleased to see that this docket has been published. It is important to keep the National List process moving forward, as some of these substances were recommended by the NOSB for inclusion on the National List as long as five years ago

We have the following comments on specific substances.

I. Crops
We support the comments from the Organic Material Review Institute regarding the inert ingredients used in pesticides proposed for the National List, and supply a number of additional remarks. Suggested deletions are in strikeout mode

205.601(m)(2) – as EPA List 3 Inerts:

- Glycerine oleate (glycerin monooleate), (CAS #~~s 111-03-5, 25496-72-4,~~ 37220-82-9) for use only until December 31, 2006.
- Tetrahydrofurfuryl alcohol (CAS #97-99-4) for use only until December 31, 2006.

OMRI correctly notes that two of the forms of **glycerine oleate** have been reclassified as EPA List 4A on the August 2004 edition of the EPA's list of inert ingredients:

CAS#	Substance	EPA List#
111-03-5	9-Octadecenenoic acid (Z)-, 2,3-dihydroxypropyl ester	4A
25496-72-4	Octadecanoic acid (9Z) monoester with 1,2,3 9-propanetriol	4A
37220-82-9	glycerine oleate	3

Therefore, the references of CAS #111-03-5 and CAS #25496-72-4 are incorrect and not needed on the National List, since they now appear on EPA's List 4A. **These two CAS numbers should be removed.** The original petition for this substance for use in pesticides was for the substance with the CAS #37220-82-9. This substance should be added to the National List with the restriction that it be removed from the National List by December 31, 2006. This deadline is needed because it corresponds to EPA's process for mandated review tolerances for both active and inert ingredients under the 1996 Food Quality Protection Act.

In addition, this inert was initially petitioned in April 2003 as needed for a formulation of micronized sulfur, used to protect organic tree fruit from fungal diseases. At that time, the petitioner described a lack of other formulated sulfur products with comparable efficacy. Since that time, a number of other micronized sulfur products have become available in organic –approved forms: Micro Sulf® (NuFarm Americas, Inc.), Thiolux® Jet (Syngenta Crop Production), Micro-Sul™ (Hondo Chemical Co), CSC 80% Thiosperse (Continental Sulfur Co.).[1] If the EPA tolerance review does not result in a reclassification of glycerin monooleate as List 4, organic farmers still have other NOP compliant formulations available for micronized sulfur products.

In the case of **tetrahydrofurfuryl alcohol**, this inert ingredient was petitioned by a company (Amvac Chemical) for use in a pesticide in 2003. The identity of this pesticide was claimed as confidential by the petitioner, and the Technical Advisory Panel review did not provide complete information due to this redaction.[2] Alternatives could not be evaluated by the NOSB. The petitioner did state in testimony at a subsequent public NOSB meeting[3] that this inert is used in their neem (a substance derived from a natural botanical source) products. There are many pesticides based on neem or neem derivatives available in organic NOP-compliant forms, with similar or better characteristics for efficacy.[4][5] Some of these were available in 2003, and more have become available since that time. The decision to permit this inert for a very limited period of time to coincide with EPA review is justified, as there are many alternatives available.

The redaction of confidential business information regarding petitioned substances is problematic, and hinders NOSB review. The National List petition requirements should be redrafted to provide guidance to petitioners, to advise them that while they may redact information, that lack of information may delay or impede review in this public process. Inert ingredients used in pesticides have a special status in the Organic Foods Production

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[1] 2005 OMRI Brand Name Product List, http://www.omri.org/OMRI_datatable.htm

[2] 2003 UC Davis, Sustainable Ag Research and Education Program, THFA TAP Review p. 1, contractors note. http://www.ams.usda.gov/nop/NationalList/THFATAP.pdf

[3] 2003 NOSB transcript, May 14, Austin Tx. page 21. Note speaker named "Amayu" describing "Amdac" (AMVAC) products. Neem is misspelled as "lean". Ecosin 3% is misspelled as "ecosyn". Product "Amazin" is misspelled as "Amazon".
http://www.ams.usda.gov/nosb/transcripts/NOSBMay2003AustinMtngTranscrips.pdf

[4] 2005 B. Caldwell, Brown Rosen E., Sideman E., Shelton A., Smart C. Resource Guide for Organic Insect and Disease Management. NYSAES, Cornell Univ. p.101-111.
http://www.nysaes.cornell.edu/pp/resourceguide/index.php

[5] 2005 OMRI, Ibid.

Act (OFPA), as they are designated as a special class of synthetics that may be approved for use in organic production.[6] However, it is very difficult for the NOSB to evaluate the availability of approved alternatives as required under OFPA Sec 6518(m)(6) if the active ingredient of the product is not disclosed, and this factor should be provided in notice to petitioners of inert ingredients.

205.601(h) As slug or snail bait,
Ferric phosphate, (CAS # 10045-86-0)

Comment: This substance should be added to the National List, according to NOSB review as suitable for organic production.

205.601 (n) Seed preparations
Hydrogen chloride (CAS # 7647-01-0) for delinting cotton seed for planting.

Comment: This substance should be added to the National List, according to NOSB review as suitable for organic production.

II. Processing Substances

205.605(a) Nonsynthetics allowed:

Egg white lysozyme
L-malic acid
Microorganisms

These three substances should be added to the National List as proposed.

205.605(b) Synthetics allowed:

All synthetics proposed for listing under 205.065 have been given a restriction that the NOSB did **not** advise: "restricted to handling agricultural products labeled 'made with organic ingredients.' " No explanation was given in the *Federal Register* for this, though it appears that the NOP sought to address the Court of Appeals order in the case *Harvey v. Johanns.* In view of the recent Congressional action to amend OFPA, this restriction should be re-evaluated. In addition, the Court order did not specifically apply to substances used as sanitizers and cleaners, and these types of substances should be considered for a separate category on the National List, regardless of status of other synthetics.[7]

[6] 1990 Organic Food Production Act. Sec. 6517(c)(1)(B)(ii)

[7] Dinerstein. P. Nov. 2005. (Counsel to A. Harvey). Impact of Harvey-Johanns Ruling – publ. comm. citing final court ruling. "The court judgment applies only to synthetic *ingredients* and *processing aids*, not to equipment cleansers, packaging materials, storage, or substances required by other regulatory schemes such as added vitamins and minerals and chlorine in water in accordance with the Safe Drinking Water Act**.** The regulations define "ingredient" as "any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed." 7 CFR 205.2. A "processing aid" is basically defined as a substance that is added to a food during processing and either is removed or is present in the finished food in insignificant amounts and has no technical or functional effect in that food."

1. **Peracetic acid / Peroxyacetic acid** – NOSB recommended this substance on Nov. 16, 2000 for direct food contact only in wash/rinse water. Allowed as sanitizer on surfaces in contact with organic food.

Recommended change to listing:
205.605(a) as sanitizer or cleaning agent:
Peracetic acid / Peroxyacetic acid (CAS #79-21-0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces. ~~Restricted to use in handling agricultural products labeled 'made with organic (specified ingredients or food group(s));" prohibited in handling agricultural products labeled "organic."~~

Comment: This substance is a useful material needed for food safety purposes. It has a better environmental profile than the widely used alternative, chlorine, which has by-products known to be carcinogenic. PAA degrades rapidly, leaves little residue, and decomposes into relatively harmless naturally-occurring substances.[8] It is used as a disinfectant in direct contact with raw whole agricultural commodities, and the'made with' annotation is not appropriate. The substance is commonly used with hydrogen peroxide and should be annotated consistently with hydrogen peroxide. This material should be added to the National List as allowed for organic products.

2. **Activated charcoal** – NOSB recommended as allowed synthetic, from vegetative sources only, for use as a filtering aid, Sept. 19, 2002

Recommended change to proposed listing:
Activated charcoal (CAS #7440-44-0; 65365-11-3)—only from vegetative sources; for use only as a filtering aid. ~~in handling agricultural products labeled 'made with organic (specified ingredients or food group(s));" prohibited in handling agricultural products labeled "organic."~~

Comment: Activated charcoal is a processing aid that is used for filtering. The TAP review supports the annotation that in order to be used in organic processing, activated carbon must come from vegetative sources. While it may be present in incidental amounts, filtering aids—whether synthetic or non-synthetic—are required to be on the National List in order to be used in *or on* organic ingredients. There are a number of other filter aids on the List, (cellulose, bentonite, kaolite clay, and diatomaceous earth) and this addition is consistent with those.

3. **Cyclohexylamine** - NOSB recommended in Oct. 2001, for use only as a boiler water additive for packaging sterilization only.
4. **Diethylaminoethanol** - NOSB recommended in Oct. 2001, for use only as a boiler water additive for packaging sterilization only

[8] 2000. Technical Advisory Panel Review, Peracetic Acid in processing, by OMRI for the NOSB, page 3. See www.omri.org

5. **Octadecylamine** - - NOSB recommended in Oct. 2001, for use only as a boiler water additive for packaging sterilization only

Recommended changes to proposed listing at 205.605(b):
Cyclohexylamine (CAS #108-91-8)—for use only as a boiler water additive for packaging sterilization. ~~Restricted to use in handling agricultural products labeled 'made with organic (specified ingredients or food group(s));" prohibited in handling agricultural products labeled "organic."~~

Diethylaminoethanol (CAS #100-37-8)—for use only as a boiler water additive for packaging sterilization. ~~Restricted to use in handling agricultural products labeled 'made with organic (specified ingredients or food group(s));" prohibited in handling agricultural products labeled "organic."~~

Octadecylamine (CAS #124-30-1)—for use only as a boiler water additive for packaging sterilization. ~~Restricted to use in handling agricultural products labeled 'made with organic (specified ingredients or food group(s));" prohibited in handling agricultural products labeled "organic."~~

Comment: Cyclohexylamine, diethylaminoethanol, and octadecylamine were intended only for use in steam used to sterilize food contact surfaces, such as bottles and caps, but should be prohibited for direct contact with food. Because they are miscible in water and form azeotropes (solutions that have the same boiling point as water, and therefore cannot be separated by distillation), they become part of the food. This limited use should be reconsidered in the next sunset review period to evaluate progress made in replacing use of volatile boiler chemicals in organic food processing.

6. Ammonium Hydroxide
Ammonium hydroxide should **not** be added to the National List at this time. The proposed listing gives a expiration date of October 21, 2005, and this recommendation was made in Oct. 2001. Processors have managed without use of this substance in the last four years, and there are a number of alternatives to ammonium hydroxide for boiler maintenance.[9] This is a volatile substance used in boiler water that carries over into organic food. It is permitted by FDA for use in milk processing, and has contact in organic milk that is subject to Ultra-High Temperature pasteurization process.

7. Tetrasodium Pyrophosphate
This item should be either be **tabled**, for more public information, or approved only as the NOP has proposed, and limited to use in products labeled "Made with Organic Ingredients." Tetrasodium pyrophosphate (TSPP) appears as ingredients in foods beyond an incidental amount. There is not complete documentation of the NOSB decision in this case available on the NOP website. The petition and TAP review are not posted. The final Board decision is not recorded, however the NOSB handling committee

[9] 2001. OMRI. Steam Generation in Organic Food Processing Systems. http://www.omri.org/AdvisoryCouncil/boiler_background.pdf

review checklist developed for the Board meeting of April 2004 is posted and the committee documented its response to the criterion regarding function of the substance.

Question: " Is the primary use to improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]"

Committee Response: "TAP – TSPP – reviewer comment; page 5; Phosphates stabilize proteins during processing so the (sic) improve finished product texture. Petition: page 4; Intended use as stated in the proposed annotation and specific uses in this petition are primarily not as a preservative, or to recreate flavor, color or texture. Its use as a dough conditioner and pH agent is indispensable because it greatly improves protein process flow… Yes, the TAP does indicate that it use is for texture but it does not state to recreate texture."

Comment:
The petitioner testified in April 2004 that this substance is used to condition the dough, so that it can be extruded mechanically in a proprietary process to produce texturized vegetable protein. The NOSB committee's argument that this use does not "recreate" texture, but "creates" it is semantic and misses the point – this is an additive used solely for the ease of manufacturing to provide texture to a product. It "recreates" texture in that it attempts to create a meat-like consistency from a grain product.

The NOSB adopted criteria for determination whether a substance is "consistent with organic farming and handling" (OFPA 6518(m)(7)) in April 2004, but does not appear to have applied these criteria to TSPP. This included the question: "Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?" TSPP is used to lend texture to an imitation meat product, which does not meet the criterion of "authenticity." As a processing aid that is exempt from labeling in the final product under FDA regulations, the inclusion of TSPP in organic products without clear consumer identification presents additional concerns, as consumers will not know this synthetic is in fact in the product, used for artificial texture.

Consumers expect a limited number of synthetics in products labeled organic, as was clearly demonstrated by the recent large number of public comments (estimated at over 300,000) submitted to Congress in opposition to a change in OFPA to permit synthetics in processing. This is not a suitable material to add to the National List for organic processing. It is not approved by any other international organic standard, and allowance of this form of phosphate additive will provide justification for the many hundreds of other forms of phosphate food additives. The current National List has a narrow allowance for basic calcium phosphates used in leavening, and one use of sodium phosphate in dairy products. Potassium phosphate is only allowed for "made with organic" products, and TSPP should be similarly restricted. Consumers that want to buy meat analog products produced with the aid of a synthetic dough conditioner should be able to choose this based on an accurate label claim that is not misleading.

The annotation for "use only in textured analog meat products" is vague. This expression is not a well-defined food term. The absence of an NOP or FDA definition leaves its

applicability unclear. It could be interpreted to mean that any grain-based product that makes an artificial meat claim may qualify under the NOP. If this substance is retained in the final rule, the annotation should be dropped, in favor of the following, which will provide consumers with clear information and choice:

Tetrasodium pyrophosphate, for use in products labeled "made with organic (specified) ingredients", provided it is included in the ingredients list of the final product.

8. Sodium Acid Pyrophosphate

Sodium acid pyrophosphate (SAPP) was reviewed during the May 2003 NOSB meetings. The NOP Petitioned substances website, currently states "NOP returned this recommendation to the NOSB for further documentation. No further action will be taken until the requested documentation is received. The reader is reminded that use of this material is prohibited."

A serious problem exists regarding documentation of this decision. The NOSB meeting transcript describes a supplemental TAP review conducted for sodium acid pyrophosphate petition that did not address the processing criteria, and did not address the issue of international recognition of this substance. [10] This review has never been made available to the public. There is no documentation of the decision using the checklist developed for all criteria. This **proposed listing should be deferred** until supporting information for SAPP can be opened to a fair public review. All information supporting the SAPP decisions should be publicly available for comment prior to any listing in a final amendment to the National List.

The petitioned use of this substance is for use as a leavening agent in refrigerated dough, such as cake donuts and biscuits, for ease of manufacturing, in order to have a slower leavening time than would be provided from other leavening agents on the National List. The petitioner stated that manufacturers needed to keep dough up to several weeks in refrigerated cases. [11] This use raises questions about the essentiality of this use, and whether products made on a fresher basis would be an alternative to using this leavening substance. Again, consumers expect limited synthetics in organic processed food, and this use for ease of manufacture may be a valid reason to permit it only for substances labeled "Made with Organic Ingredients. "

9. Other substances Not Included

There are a number of outstanding NOSB recommendations that have not been included in a docket. It would be helpful to have a statement from NOP regarding the status of

[10] 2003. NOSB Meeting Transcript, May 13, pp 307-310.
http://www.ams.usda.gov/nosb/transcripts/NOSBMay132003AustinMtng.pdf
[11] 2003 NOSB Meeting Transcript. May 14, p 28
http://www.ams.usda.gov/nosb/transcripts/NOSBMay2003AustinMtngTranscrips.pdf

these items. The livestock materials were recommended in Sept 2002, and resolution is needed regarding these substances needed for humane animal health care.

205.603- Synthetic substances allowed in organic livestock production

Activated carbon
Adrenaline
Atropine
Bismuth subsalicylate
Butorphanol
Calcium borogluconate
Calcium proprionate
Epinephrine
Excipients for livestock medications
Flunixin
Furosemide
Kaolin Pectin
Magnesium oxide
Magnesium hydroxide
Moxidectin
Peracetic acid
Pheromones
Poloxalene
Potassium sorbate
Propylene glycol
Tolazoline
Xylazine

205.606 Nonorganically produced agricultural products …..for use in processed products
Gelatin
Shellac, Orange—unbleached

Gelatin and shellac both had complete TAP reviews, and the NOSB voted to list them in 205.606 on May 07, 2002. These should be added promptly to 205.606, as we now have clarification that all non-organic agricultural substances must appear on the National List in order to be used in products labeled organic.

Respectfully submitted,

Emily Brown Rosen
Organic Research Associates, Titusville NJ

Eric Sideman
Greene, Maine